Medtronic Sofamor Danek
ANATOMIC PEEK™ CERVICAL FUSION SYSTEM
510(k) Summary – K130177

September 2013

Company: **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738

SEP 2 3 2013

Contact: **Lee Grant**
Distinguished Regulatory Affairs Advisor

Proposed Proprietary Trade Name: ANATOMIC PEEK™ CERVICAL FUSION SYSTEM

Classification Name(s): Intervertebral Body Fusion Device (per 21CFR Section 888.3080); Product Code: ODP

Description: The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is designed for use as a cervical interbody fusion device. The device is manufactured from polyetheretherketone (PEEK OPTIMA™) and is to be used with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The ANATOMIC™ PEEK CERVICAL FUSION SYSTEM consists of hemi-cylindrical cages of various widths, heights and depths. The hollow geometry of the implants allows them to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Indications for Use: The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK™ device is to be used with supplemental fixation. The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open anterior approach.

Summary of the Technological Characteristics: The purpose of this 510(k) submission is to seek clearance for the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative to autogenous bone graft. No changes have been made to the actual implants.

Identification of Legally Marketed Devices: The components contained in this application are identical to those cleared in K112444 (SE 11/15/11) with the exception of

the inclusion of allogenic cancellous and/or corticocancellous bone graft as an alternative bone graft material.

Discussion of Supporting Retrospective Clinical Data and Non-Clinical Testing: Published retrospective clinical data for the cervical interbody fusion devices similar to the ANATOMIC PEEK™ CERVICAL FUSION SYSTEM was provided in support of this application. The published clinical outcomes demonstrated that the use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, in anterior cervical interbody fusion procedures to treat patients diagnosed with cervical disc disease as defined above poses no new risks to patients. No changes were made to the existing devices, nor were any new components added to the system. Therefore, no additional testing was required or performed.

Conclusion: The design features, materials used, manufacturing and sterilization methods are equivalent to the previously cleared ANATOMIC PEEK™ CERVICAL FUSION SYSTEM components with the exception of broadening the indications to include the aforementioned use of allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an alternative graft material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - W066-G609
Silver Spring, MD 20993-0002

September 23, 2013

Medtronic Sofamor Danek USA, Incorporated
Mr. Lee Grant
Distinguished Regulatory Affairs Advisor
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K130177
Trade/Device Name: ANATOMIC PEEK™ Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: August 7, 2013
Received: August 14, 2013

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

for

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K130177

Device Name: ANATOMIC PEEK™ CERVICAL FUSION SYSTEM

Indications for Use:

The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK™ device is to be used with supplemental fixation. The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is also required to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and is to be implanted via an open anterior approach.

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices